

### **Remarks**

Claims 48 to 76 are pending in this application. Claim 69 is withdrawn. An amendment to claim 75 to correct a typographical error is submitted herewith.

### **Allowable subject matter**

On page 7, the Office Action states that claims 66, 67, 73 and 74 are objected to as being dependent upon a rejected base claim, but that these claims would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicants would like to thank the Office for this acknowledgement of patentability of claims 66, 67, 73 and 74.

With respect to the remaining claims, applicants would like to submit the following remarks:

### **35 USC §112, second paragraph rejection**

On page 2, the Office rejected claims 75 and 76 under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular, the Office expressed the opinion that claims 75 and 76 refer to the vector and the promoter from claim 48. The Office, however, noted that there is more than one vector in the claim. Thus, the Office expressed the opinion that it is unclear whether one or both vectors from claim 48 are being limited by a low expression promoter.

Applicants acknowledge that a spelling mistake was made in claim 75 as indicated below by strikethrough:

*The vector of claim 48, wherein said promoter is in (b) is a promoter that confers low level expression*

A corrected version of the claim is submitted herewith (see specification, e.g., page 23, lines 14 and 15 for support).

Both, claims 75 and 76 are understood or do refer to the "promoter in (b)" of claim 48. Claim 48 (b) refers to a particular vector, namely the bait vector. Accordingly, applicants submit that it is clear that reference is made to the bait vector.

The Manual of Patent Examining Procedure (MPEP) clarifies that all that is required for a particular phrase to be definite is a reasonable degree of clarity and particularity. The

MPEP also emphasizes that the definiteness of claim language must be analyzed in light of the content of the particular application disclosure and the claim interpretation that would be given by those possessing the ordinary level of skill in the pertinent art at the time the invention was made (MPEP §2173.02). The MPEP refers to *Metabolite Labs.* in which the CAFC stated that only when a claim remains insolubly ambiguous without a discernible meaning after all reasonable attempts at construction must a court declare it indefinite. *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1366 (Fed. Cir. 2004).

Applicants submit that claims 75 and 76, in particular, when viewed in conjunction with the disclosure, readily meet the threshold requirement of clarity and particularity which is all that the MPEP prescribes. In addition, applicants respectfully submit that the amendment to claim 75 does not raise an issue of new matter or present new issues requiring further consideration or search (MPEP §714.13).

### **35 USC §102(b) Rejection**

On pages 3 and 4, the Office continues to reject claims 48 to 65 under 35 USC §102(b) in view of Staglar et al. (PNAS 95:5187-92 (1998), hereinafter "Staglar"). The Office added new claims 71 and 72 to this rejection. The Office expressed the opinion that every element of the claims is disclosed by this reference.

The Office acknowledged applicants' argument that the rejected claims recite that the bait and the prey vectors are maintained episomally.

Claim 48 recites:

"(d) . . . wherein both the bait vector and the prey vector are maintained episomally" (emphasis added)

However, the Office states that this argument is not considered persuasive. The Office expresses the opinion that Staglar teaches "both bait vectors that are integrated, as well as maintained episomally." The Office referred to page 5190, second paragraph of this publication.

Applicants respectfully disagree with the Office's opinion. In particular, applicants submit that Staglar's bait construct is integrated (see argument in response of July 23, 2007, page 20).

This is supported on, e.g., page 5189, left column ("The resulting fusion genes were

integrated . . .") (see response of July 23, 2007, page 20)) and page 5187, right column, last paragraph ("...pRS305 (Dwbp1-Cub-PLV) was integrated at the single Spel site into the WBP1 gene...").

Applicants have reviewed the reference as a whole and in particular page 5190, second paragraph, as cited by the Office and have not found any reference to a bait vector that is maintained episomally as required by the rejected claims.

Thus, applicants respectfully submit that Stagljär does not disclose all elements of the rejected claims as required for an anticipation rejection.

### **35 USC §103(b) Rejection**

On pages 4 and 6, the Office rejects claims 68 and 70 over Stagljär (above) in view of Ehrhard et al.

The deficiencies of Stagljär have been outlined above. Applicants submit that these deficiencies are not cured by Ehrhard et al. Also, no other argumentation and/or sources with regard to the elements identified as missing from Stagljär are set forth in the Office Action. Thus, applicants submit that no *prima facie* case of obviousness has been presented by the Office.

However, applicants note, however, that on page 5191, first paragraph, Stagljär states "second, overexpression of WBP1-Cub-PLV . . . results in gene activation in the absence of Nub" (compare, e.g., elements (e) and/or (f) of claim 48). Stagljär avoids this overexpression by integrating the bait vector. Thus, applicants submit that Stagljär in fact teaches away from "curing" the deficiencies outlined above.

In view of the above, applicants, while disagreeing with the Office, do not submit an argument with regard to the Office's interpretation of "synthetic alpha-factor" (for which, applicants note, humans lack a receptor) as a pharmaceutical drug as set forth on page 6 of the Office Action. Applicants will submit such an argument if this case should require further prosecution.

Applicants submit that none of the above raises an issue of new matter or presents new issues requiring further consideration or search (MPEP §714.13). Thus, entry of this response is respectfully requested and issuance of a notice allowance is earnestly solicited.

The Office is urged to call the undersigned at the number provided below with any

questions or concerns or to resolve any open issues.

No fee is believed to be due. However, any petition required for consideration of this paper is respectfully requested herewith and the Commissioner is authorized to charge deposit account 50-3135 for fees that might be required for such consideration.

Respectfully submitted,

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